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EXAMINER

LUSTUSKY, SARA

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/612,325	Applicant(s) DEEM ET AL.	
	Examiner Sara Lustusky	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
4a) Of the above claim(s) 11-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/26/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10, drawn to a method for treating a body lumen of a patient, classified in class 600, subclass 30.
 - II. Claims 11 and 16, drawn to a device comprising two or more magnets or magnetizable components, classified in class 335, subclass 306.
 - III. Claims 12 and 13, drawn to a device comprising an elongated catheter and a magnetic delivery device comprising an elongated tube with at least one needle, classified in class 604, subclass 57.
 - IV. Claims 14 and 15, drawn to a device for magnetizing magnetizable components or particles comprising a catheter and a permanent or electromagnet, classified in class 600, subclass 421.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the magnetizable components or magnets may be used in materially different processes including bracing objects against a metal surface.

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3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the device of Invention III, comprising an elongated catheter and an elongated tube with at least one needle, can be used to inject an area of the body with radioactive substances.

4. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the device can be used to remove magnetizable materials from the body such as foreign objects or metal implants.

5. Inventions II and III are related as products that share an alleged common utility of treating a body lumen but the common utility is not linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be used to perform another utility. In this case, the magnetizable components or magnets of Invention II can be used to brace objects against a metal surface. Furthermore, the device of Invention III can be used to inject an area of the body with radioactive substances.

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6. Inventions II and IV are related as products that share an alleged common utility of treating a body lumen but the common utility is not linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be used to perform another utility. In this case, the magnetizable components or magnets of Invention II can be used to brace objects against a metal surface.

7. Inventions III and IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination IV has separate utility such as magnetizing magnetizable components or particles disposed in the wall of a body lumen. See MPEP § 806.05(d).

8. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

9. During a telephone conversation with Attorney James Heslin on April 6, 2006 a provisional election was made without traverse to prosecute the invention of a method for treating a body lumen of a patient comprising placing at least two magnetic or magnetizable devices within a wall of the body lumen, claims 1-10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-16 are

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withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

11. The Information Disclosure Statement (IDS) submitted on 4/26/04 is acknowledged since the IDS complies with 37 CFR 1.97 and 1.98, the references submitted therein have been considered.

Claim Objections

12. Claim 1 is objected to because of the following informalities: the limitation recited in line 4, "wherein the attraction between the magnetic devices at least partially constricts the lumen", should be clarified. This statement should clarify that the magnetic devices are what cause the constriction and not the attraction itself. Appropriate correction is required.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. Claim 1 - It is unclear whether only "the magnetic devices", at lines 3 and 4, are being claimed in view of the alternative limitation "at least two magnetic or magnetizable devices" at line 2.

16. Claim 2 recites the limitation "the magnetic devices" in line 1. In view of the alternative limitation "the at least two magnetic or magnetizable devices" of claim 1, it is unclear whether the method definitely includes only "the magnetic devices" recited at line 1 or if the method may be performed using "magnetizable devices".

17. Claim 3 recites the limitation "the at least two devices are not magnetized when implanted into the wall of the patient's esophagus" in line 1. In lines 4-5 the limitation "the implanted at least two devices" is recited and in line 6 the limitation "the at least one of the two devices" is recited. Regarding the limitation at line 6, it is unclear whether there are definitely only two devices or if there may be more. It is further unclear whether the esophagus as recited in line 2 is consistent with the limitation "the body lumen" as recited in claims 1 and 2.

18. Claim 4 recites the limitation "the at least two magnets" in lines 2-3 There is insufficient antecedent basis for this limitation in the claim. Regarding the limitation "the

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at least one of the two devices” recited in lines 9-10 renders the claim indefinite. It is unclear whether “the two devices” refers to the magnetizing device, the pressure sensing device, or the at least two magnetic or magnetizable devices; and if the magnetic or magnetizable devices are being referred to, it is unclear if there are only two or if there may be more. Furthermore, claim 4 recites the limitation “sensing a pressure within the body lumen” in line 6. It is unclear in view of claim 3 whether this body lumen is the esophagus. Moreover, it is unclear whether the “location” referred to in line 4 is the location of the pressure sensing device or the preselected location where the at least two devices are placed.

19. Claim 6 recites the limitation “near the implanted at least two magnets” in lines 3 and 4. There is insufficient antecedent basis for this limitation in the claim. Furthermore, in view of the limitation in lines 4-5, it is unclear whether a pressure has been sensed within the esophagus.

20. Claim 8 recites the limitation “the at least two magnetic devices” in lines 1-2. In view of the alternative limitation “the at least two magnetic or magnetizable devices” of claim 1, it is unclear whether there are definitely only “magnetic devices” or if there may be “magnetizable devices”.

21. Claim 9 recites the limitation “the at least two magnetic devices” in lines 1-2. In view of the alternative limitation “the at least two magnetic or magnetizable devices” of claim 1, it is unclear whether there are definitely only “magnetic devices” or if there may be “magnetizable devices”.

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22. Claim 10 recites the limitation "the at least one of the two magnetic devices" in lines 1-2. In view of the alternative limitation "the at least two magnetic or magnetizable devices" of claim 1, it is unclear whether there are definitely only "magnetic devices" or if there may be "magnetizable devices". Furthermore, it is unclear from the limitation "the at least one" which of the plurality is being referred to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

23. Claims 1, 2, 8 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilk (U.S. Patent 6730014 B2). Wilk teaches a method for treating a body lumen of a patient, the method comprising placing at least two magnetic (24) or magnetizable devices (24) within a wall of the body lumen (ES) at a preselected location, wherein the magnetic devices (24) are attracted to one another and wherein the attraction between the magnetic devices (24) at least partially constricts the lumen (column 5, lines 29-36).

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24. Claim 2 – The method of Wilk further teaches inserting an endoscope (12) having a delivery device (22) into the body lumen; advancing the endoscope (12) to position the delivery device (22) near the preselected location; and implanting, with the delivery device (22) the at least two magnetic (24) or magnetizable devices (24) into the wall of the body lumen (Figure 1c)(Claim 11).

25. Claim 8 – The method of Wilk further teaches placing at least two magnetic devices (24) on opposite sides of a feature to be closed (Claim 1) wherein said feature is located in the esophagus (ES)(Figure 1c)(Claim 4).

26. Claim 10 – The method of Wilk teaches that at least one of the two magnetic devices comprises magnetic particles (24)([0059]).

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

28. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (U.S. Patent 6730014 B2) in view of Kim (U.S. Patent 6604529 B2). The method of Wilk teaches treating a body lumen of a patient by placing at least two magnetic (24) or magnetizable devices (24) using an endoscope (12) with a delivery device (22) within a wall of the body lumen, wherein the attraction between the magnetic devices (24) at

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least partially constricts the esophagus (ES) (Figure 1b, 1c)(Claim 1). However Wilk does not teach the method of implanting unmagnetized devices that are magnetized later.

29. Kim teaches a method wherein the at least two devices (10) are not magnetized when implanted into the wall of the patient's tissues (20) (column 5, lines 56-61), the method further comprising: positioning a magnetizing device (40) at a location near the implanted at least two devices (Figure 5); and magnetizing the at least one of the two devices (column 7, lines 17-22).

30. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the method of Wilk to implant magnetizable devices in the unmagnetized state as taught by Kim because it provides more control over the activity of the magnetism when compared to permanently magnetic devices which either attract or repel each other continuously. Furthermore, by controlling the magnetism of the implanted magnetizable devices, necrosis of the tissues may be avoided.

31. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (U.S. Patent 6730014 B2) in view of Silverman et al. (PGPUB US 2002/0028979 A1) and further in view of Siemens AG (DE 30 11 742 A1). The method of Wilk teaches treating a body lumen, including the esophagus (ES), of a patient by placing at least two magnetic (24) or magnetizable devices (24) within a wall of the body lumen, wherein the attraction between the magnetic devices (24) at least partially constricts the lumen

(Figure 1B)(Claim 1). However Wilk does not teach implanting magnetic or magnetizable devices in a radial pattern within a retaining ring.

32. Silverman et al. (PGPUB US 2002/0028979 A1) teaches a method for forming valve-like mechanisms in the esophagus by inserting implants (71) into the tissue (27) near or around a body lumen or sphincter [0061]. The implants (71) may be placed into the tissue (27) in a radial pattern around the lumen (Figure 8) or a ring implant (72) can be inserted into the tissue (27) (Figure 9).

33. It would have been obvious to use the method of Wilk to implant the magnetic or magnetizable devices of Wilk in the radial or ring pattern of Silverman et al. because these patterns create valve-like mechanisms to aid the lumen or sphincter (Silverman et al. [0061]). In particular when implanted into the wall of the esophagus it forms a type of prosthesis capable of inhibiting reflux from the stomach (Silverman et al. [0063]).

34. Siemens AG (DE 30 11 742 A1) teaches the use of a ring of at least two individual magnetic elements (described as groups on page 8 line 36 and page 9 lines 1-2) comprising at least four magnets (21) contained within a retaining ring (24), wherein the retaining ring (24) is configured for placement within the wall of a body lumen and the at least four magnets (21) attract one another in a radial pattern (20) to constrict the retaining ring (24) (Figure 2) (as described on page 8, lines 21-36, and on page 9, lines 1-6).

35. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the method of Wilk to implant the magnetic or magnetizable devices of Wilk in the radial or ring pattern of Silverman et al. within a retaining ring as

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taught by Siemens AG to keep the individual magnetic or magnetizable components in place within the tissue and to protect the body from corrosion of the magnetic or magnetizable components.

Allowable Subject Matter

Claims 4, 5, 6 and 7 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter:

Claim 4 defines over the art because none of the prior art of record defines adjusting the magnetic power of at least one of the two devices, based on a sensed pressure. Claims 5, 6 and 7 also define over the art because they depend from claim 4.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


S.L.


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